K103290

Edlen Imaging, LLC
3707 North 7th Street, Suite 125
Phoenix, AZ 85014

510 (k) Summary

As required by CFR section 807.92 [c]

SEP 19 2011

General Description

Date:	October 11, 2010
Applicant/Sponsor:	Edlen Imaging LLC 3707 North 7th Street, Ste 125. Phoenix, Arizona, USA 85014
Contact Person:	Felix Hovsepian
Telephone:	1-602-524-9611
e-mail:	edlenimg@gmail.com

Device Names

Trade Name:	Edlen Imaging - Gemini DUSB
Common Name:	Gemini Digital X-ray Sensor
Classification Name:	Unit X-ray sensor Intraoral to capture - Extra Oral X-ray source, per 21 CFR 872-1800. Regulatory Class II. Product Code: MUH.

Predicate Devices

Company	Device Name	K-Number
Schick Technologies	CDR	K072134
Suni Medical Imaging, Inc	Suni Ray II	K070219

Product Description

The Gemini sensor is an indirect light converting digital X-ray detector. Incident X-rays are converted to visible light by a scintillating device, (material) such as CsI (Cesium Iodide), the light is coupled optically to a light detection imager which is based on CMOS technology.

The design of the sensor allows for automatic detection of incident X-rays to generate a digital data which when coupled with a software program will display images used for dental intra-oral applications.

The Gemini Digital x-ray sensor supports USB 2.0 Direct connectivity to personal computers and or laptops, hence the name Gemini DUSB.

The Gemini sensors employ built-in dedicated electronics and sensor software driver, to allow connectivity to a variety of software packages. The Gemini sensors are coupled with the currently marketed software, Apteryx XrayVision, K983111.

Intended Use of the Device

The Gemini sensor is a dedicated USB-driven device intended to acquire dental intra-oral radiographic images. The sensor is operated by Radiologists, Dentists, Dental Assistants and or like healthcare professionals, who are duly trained and competent to both operate the Gemini sensors and take Dental X-ray radiographs. Intra oral positioning of the sensor is accomplished by the use of dedicated intra-oral positioning devices that facilitate the accurate alignment of the X-ray beam.

Technological Characteristics

The Gemini Digital x-ray sensor is to be used as an intraoral receiver of x-ray in Dental radiography.

The Gemini system shares the same indication for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed above.

There are many independent manufacturers of intraoral x-ray dental radiography systems in the US today. The first is the CDR system by Schick Technologies (K072134) and the second is the Suni Ray II by Suni Medical Imaging (K070219)

A comparison table for the different systems is available in the section on Substantial Equivalence.

The device has been tested by a third party and found to meet the international safety standards established by the IEC (60601-1), further details available in the section on conformance).

Software

The Gemini Digital system is provided with imaging software provided by:

Apteryx, Inc.
334 White Pond Drive, Suite A
Akron Ohio 44320
Tel: (330) 867 6077
K983111 (See Attachment 9)

Conclusion

Edlen Imaging's Gemini Digital x-ray sensors are substantially equivalent to other legally marketed devices in the United States of America. The Gemini Digital x-ray sensors are as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the Gemini Digital x-ray sensors are deemed to be substantially equivalent to the predicate devices in intended use and technical characteristics to those of:

c. *SuniRay II Digital Radiographic System marketed by Suni Medical Imaging, Inc.*

and

d. *The CDR system marketed by Schick Technologies, Inc*

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Dr. Felix Hovsepian
CTO
Edlen Imaging, LLC
3707 North 7th Street, Suite 125
PHOENIX AZ 85014

SEP 19 2011

Re: K103290
Trade/Device Name: Gemini DUSB Digital x-ray
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 15, 2011
Received: August 22, 2011

Dear Dr. Hovsepian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103290

Device Name: Gemini DUSB Digital x-ray

Indications for Use:

Edlen Imaging's Gemini DUSB sensor is a USB-driven digital X-ray sensor that acquires dental intra-oral X-ray images. The sensor will be operated by trained dental and related healthcare professionals to acquire dental intra-oral radiographs.

The Gemini sensor can be used either in combination with special positioning devices, to facilitate alignment with the x-ray beam, or it may also be positioned manually.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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